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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/424,482
Filing Date: February 29, 2000
Appellant(s): CHOO ET AL.

Joe Liesbeschuetz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/20/2006

appealing from the Office action mailed 7/25/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. However, upon careful reconsideration, the rejection of claims 6 and 32 under 35 USC 112, second paragraph is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Greisman, H.A. "A general strategy for selecting high-affinity zinc finger proteins for diverse DNA target sites", Science, vol. 275, (January 31, 1997), pp. 657-661.

Choo, Y. "Designing DNA-binding proteins on the surface of filamentous phage", Current Opinion in Biotechnology, vol. 6, (1995), pp. 431-436.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112, first paragraph

Initially as noted by appellants at page 5 of the Brief, claim 7 should have not been applied to this rejection. The inclusion of claim 7 in this rejection is regretted.

Thus, claims 1-2, 6, and 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim 1 drawn to the randomization of amino acids at position 2 of a zinc finger (i.e., D, A, R, Q, H, K, S, N) in the context of co-randomization of each of the remaining

positions, particularly position 6, having no define amino acids is not supported in the as-filed specification. Similarly, claim 30 with a random amino acid at position 6 restricted to the Markush groups (i.e., R, W, V, A, E, K, N and T) in combination with the other positions having no define amino acids, particularly position 2, is not supported by the original disclosure. The specification, as originally filed, recites random ***specific*** amino acids for each of positions -1 to 6, particularly for the positions 6 and 2 pair. MPEP 714.02 states that applicants specifically point where in the specification the new claimed limitation appear. [See further the Response to Arguments, below.)

Claim Rejections - 35 USC § 103

Claims 1-2, 6-7 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisman et al in view of and Choo et al.

Greisman et al discloses at page 275, the abstract a library of zinc finger that extends to the 9 to 10 base pair target site. The amino acid residues at positions -1, 1, 2, 3, 5 and 6 in each of the alpha helices (Fig. 1) of the three finger of the zinc finger are random residues. See further Fig. 2B where a random residues at Finger 1 is at positions -1, 2, 6 and Finger 2 at -1, 2, 3 and at Finger 3 at -1, 2 and 6. Greisman

does not disclose that randomization is at least at positions 6 and 2 of the adjacent first and second fingers, respectively. Choo discloses at page 432, col. 2 a library of a zinc finger in which the seven positions (-1, 1, 2, 3, 5, 6 and 8) were random residues. Choo further discloses at page 433, last paragraph that the best combination of fingers was selected en bloc using the entire 9bp target site. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a library wherein positions 2 and 6 are random residues as taught by Greisman. Greisman already suggests that at least at one position of -1, 1, 2, 3, 5 of the first finger and at least one position -1, 1, 2, and 3 at the second adjacent finger can be random residues. It would further be obvious to have a library wherein the randomization is extended at positions 2 and 6 (i.e., en bloc) as taught by Choo in the library of Greisman. The advantage provided by Choo provides the motivation to do the modification to one having ordinary skill in the art.

(10) Response to Argument

35 USC 112, first paragraph

Appellants submit that the specification does reasonably evident appellants' possession of a zinc finger library, randomized at positions 6 and 2 of adjacent first and second

fingers, respectively in which randomization at position 2 is confined to D, A, R, Q, H, K, S and N or randomization at position 6 is confined to R, Q, V A, E, K, N and T, without necessarily requiring randomization at any other position or confining randomization at each of the remaining positions -1, 1, 2, 3, 5 and 6 to the Markush group of amino acids specified for that position in claim 7. The specification states at page 11, lines 13-14, it is not necessary for each finger to be randomized at each of the positions [-1, 1, 2, 3, 5 and 6] given in Table 1.

In reply, the specification at the time of filing requires that the random residues at least at positions 6 and 2 are those specifically recited therein. It does not support that either position 2 or 6 with the specific random residues is combined with any random residues at said position 6 or 2. It does not support the claim to the specific random residues at position 2 and broadly any random residues (i.e., with no defined residues) at position six. (The present claim 1 appears to be a subgenus of the original claim, which recites broadly any kind of random residues at each of the positions -1 to 6 and a species of the random residues as recited in claim 7).

Appellants state that in addition the specification provides a table of amino acids "preferably selected" to appear

at each position (p.11, lines 3-14). In using the term "preferably selected" the specification conveys that position 2 is preferably occupied by the recited amino acid, but can less preferably be occupied by other amino acids. Likewise position 6 is preferably occupied by the recited amino acids but can also be occupied by other amino acids. Similar preferred groups of amino acids are provided for other positions. The table does not state that if one position is occupied by a preferred group of amino acids, then every other position must also be occupied by its preferred group of amino acids. To the contrary, the specification states that it is not necessary for each listed position to be randomized. In other words, the preferences for amino acids at various position listed in the table do not have to apply simultaneously or not at all.

In reply, the specification at page 8,line 26 up to page 9, line 10 states that at least a pair position (i.e., 2 and 6) be random residues. If the disclosure of the specific residues, as of the filing date, is only the preferred residues then, the as-filed specification does not also provide support for the ***other*** non-preferred residues comprised in said positions 2 and 6. It is of interest to note appellants' statement at page 7 of the Brief which states "…a library in which positions 6 and 2 in adjacent fingers are ***simultaneously*** randomized…"

The original disclosure does not only provide support for the claimed combination of a specific random residue at e.g., position 2 with the non-preferred random residues at e.g., position six. But also does not describe the amino acid different residues comprised in the non-preferred residues as of the filing date.

35 USC 103

Appellants state that Greisman discusses an iterative strategy for making zinc finger protein, which involves randomizing and selecting one finger at a time. The method is iterative in that finger(s) that have previously been selected provide context for selection of another of another finger.

Choo is stated to discuss a different strategy for making zinc finger proteins, in which the individual fingers of the zinc finger protein are randomized and selected independently of each other. After selection of individual fingers, random combinations of the fingers are selected *en bloc*. The en bloc selection partly circumvents the problems of position and context.

In reply, appellants' arguments with respect to Greisman and Choo are not commensurate in scope with the claims. The claims recite a zinc finger polypeptide ***library*** and not to a

method of making or to the strategy of making the zinc finger proteins.

Appellants argue that the cited references do not teach or suggest the groups of amino acids recited in claim 1 and claim 30 to which partial randomization of amino acids is restricted to D, A, R, Q, H, K, S and N in claim 1 and R, Q, V, A, E, K, N and T in claim 30. Greismn randomizes a single finger at a time and therefore fails to disclose a library in which positions 6 and 2 in adjacent fingers are simultaneously randomized. In randomizing a single finger at a time, Greisman teaches to randomize in such a manner as to allow any of sixteen amino acids at each position. The four omitted amino acids are omitted as part of a strategy to avoid stop codons. Choo, like Greisman restricted randomization to 16 amino acids. Choo also omitted four amino acids. The view that omitting the amino acids (Trp, Phe. Tyr and Cys) was unfortunate teaches away from performing randomization with additional amino acids omitted.

In response, as stated above, appellants' arguments are not commensurate in scope with the claims, which do not claim the argued randomization strategy. Greisman discloses at least at page 659, Fig. 3, the different zinc finger polypeptide with random amino acid residues at position -1 up to position 6 for each of the different specific zinc finger containing

polypeptide such as the TATA box. The claimed amino acid residues in claim 7 are shown at e.g., Fig. 3 A of Finger 1 i.e., wherein 2, inter alia, is N(Asn) and 6 is also N. Figure A, for the finger 2 shows at position 2 A (ala) and position 6 as Q and A. This would then meet the claimed library with at least position 2 being a random residue at one finger and the adjacent finger with 6 having a random residue. Thus, the claimed library with the random amino acid residues includes or encompasses the library of random peptide of Greisman for each of the different fingers.

Appellants recognized that Greisman teaches random amino acids with any of sixteen amino acids at each position omitting Trp, Phe, Tyr and Cys. [Note the instant claim does not also recite these residues, unless of course this is the non-preferred residues]. It would be within the ordinary skill in the art at the time the invention was made to pick and choose from the known available sixteen amino acids disclosed by Greisman, the ones that can combine to form the instant library. Greisman discloses, or at least suggests, from the 16 amino acids the random species at each positions of the zinc finger as shown at Fig. 3. Some of the combination of amino acids includes a random residue at positions 2 and 6, which is encompassed by the instant random residues at said positions. Gresiman teaches

that each of the amino acids in the zinc finger is random amino acid that can be selected from 16 amino acids and discloses some specific ones. Choo discloses that combinations or en bloc residues of zinc fingers can be random. Therefore, the combined teachings of the prior art would have led one having ordinary skill in the art at the time the invention was made to the instant random library. To select features from the prior art to effect results expected from these features is within the purview of 35 USC 103. In re Skoner, 186 USPQ 80 (CCPA 1975).

This is especially true because the claimed composition (library) is used for the identical purpose taught by the prior art (i.e., screening for binding to the DNA target site). See In re Corkill, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985).

Appellants state that restricting the sets of amino acids at positions 2 and 6 is optimal, restriction of the set of amino acid at one position and not the other still allows the advantage of increase representation of productive combinations of amino acids at these positions and because it allows greater variation at other positions without exceeding constraints on overall library size to be achieved in part.

In reply, neither claim 1 nor claim 30 restricts the sets of amino acids at positions 2 and 6. Thus, the argument as to an

optimal library is unclear. Furthermore, the specification does not disclose that the restricted set of amino acids result in an optimal library. Rather, that the library is screened for the residues that binds to the DNA target site. Be it as it may, optimization of a given parameter is within the ordinary skill in the art. Thus, the claimed zinc finger protein library is a known library comprising of at least a random amino acids in each of the positions (-1 to 6) as taught by Greisman and Choo.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

T. Wessendorf

May 25, 2006

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